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**Qualification For *Devices*** **Form 2B**

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| Study Identification\*\* | **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **Proposal/Protocol #:**  **Version /date** | Click here to enter text. |
| **Study Title:** | Click here to enter text. | | |

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| Study Detail | **NCT#:** | Click here to enter text. | **IND # (if applicable):** | Enter if applicable. |
| **Type of Billing Plan**  (to be associated with this study) | Draft (Proposals Only)  Complete (Finalized Billing Plan) | **CMS Category and IDE#:** | Click here to enter CATEGORY.  Click here to enter NUMBER. |

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| **Section A: Approval Process by FDA Submission Date** |
| What was the FDA Submission Date  ***On/After*** January 1, 2015 (New) or  ***Prior*** to January 1, 2015 (Grandfathered Process)  ***Note***: Effective January 1, 2015, the Centers for Medicare & Medicaid Services added criteria for coverage of investigational device exemption (IDE) studies that changed from local Medicare administrative contractor (MAC) review and approval to a centralized review and approval. CMS approval is required for investigational device studies conducted at VCU. *Ref:* [*Medicare Benefit Policy Manual – Ch. 14 Medical Devices 11-6-14*](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf)  **ESSENTIAL RESOURCES supporting the approval process:**   * VCU investigators acting as the sponsor must refer to the detailed CMS submission guidance at <http://www.cms.gov/Medicare/Coverage/IDE/>. This CMS website includes updated information on where and how to submit (e.g., via email to [clinicalstudynotification@cms.hhs.gov](mailto:clinicalstudynotification@cms.hhs.gov) -- requires specific file naming standards). * [Medicare Coverage IDE Study Criteria Checklist and Crosswalk [PDF, 83KB]](http://www.cms.gov/Medicare/Coverage/IDE/Downloads/IDE-Study-Criteria-Crosswalk-Sep-2014.pdf) * [MM8921 – Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies [PDF, 69KB]](http://www.cms.gov/Medicare/Coverage/IDE/Downloads/MM8921.pdf) * [CMS-Approved IDE Studies](https://www.cms.gov/medicare/coverage/ide/approved-ide-studies.html) * [VCU Faculty-Held INDs or IDEs](http://www.research.vcu.edu/IND_IDE/index.htm) |

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| **Section B: Submission Identification**  Select one device status, review type, and follow corresponding guidance. | | |
| **Device Status**  (SELECT ONE) | **Type** | **CMS Guidance** |
| **Post Market FDA Approved Device** – Use as Indicated “**On-Label**” | Post Market FDA-Approved Device. This device will be used as indicated on the FDA-approved labeling. | When Post Market FDA-Approved Devices will be used as indicated on the FDA-approved labeling, CMS written approval is not required in order to bill Medicare for routine care items. VCU may request a letter (as a courtesy) from the local contractor. The letter will acknowledge participation in a Post Market FDA Approved Device study and refer the provider to [CMS Claims Processing Manual, Publication 100-04, Chapter 32](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html). Refer to [Palmetto GBA](http://www.palmettogba.com/). |
| Investigational Device under [Category A IDE or Category B IDE](http://www.cms.gov/Medicare/Coverage/IDE/) | **Category A IDE** – Experimental devices where the ‘absolute risk’ of the device has not been established.  ***Or***  **Category B IDE** - Non-experimental investigational devices determined to be ‘reasonable and necessary’ | **If the FDA submission was *On/After* January 1, 2015:** Study sponsor must submit a request for CMS review and approval (or agree to pay all study-specific costs). If the VCU investigator is the study sponsor, the VCU investigator assumes this responsibility as outlined in [Medicare Benefit Policy Manual Ch. 14 - Medical Devices](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf)  **If the FDA submission was *Prior* to January 1, 2015:** VCU study team must request approval through the CMS contractor and develop the clinical budget accordingly. Refer to [Palmetto GBA](http://www.palmettogba.com/).  Organ Care System (OCS) – Liver console and Perfusion set.  [CMS-Approved IDE Studies](https://www.cms.gov/medicare/coverage/ide/approved-ide-studies.html) – CMS approval letter provided by sponsor, dated December 20, 2016  FDA letter Dated November 16, 2016. |
| Investigational Device Under a [510(k) Premarket Notification](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)  **or**  Investigational Device under a [Premarket Approval (PMA)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm) | This device been approved for investigation under a 510(k) Premarket Notification or Premarket Approval (PMA)  **510(k) #:** Click here to enter #.  **PMA #:** Click here to enter #. | |
| Investigational Device **-** [Coverage with Evidence Development (CED)](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/) | Is this Investigational device study registered for the collection of post service data on the [CMS CED Page](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/)?  **Yes** - See CMS Guidance (next column). | This study has been approved by CMS for Coverage with Evidence Development. VCU study team must attach supporting documentation from the [CMS CED page](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/). |
| Investigational Device - [Non-Significant Risk (NSR)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#non_sig_risk) | Has the local IRB approved the Investigational device as NSR?  **Yes** - See CMS Guidance (next column). | Following local IRB-approval of the device as NSR, device as “non-significant risk”, VCU study team must request approval through the CMS contractor and develop the clinical budget accordingly (unless sponsor pays for ALL study-specific items). Refer to [Palmetto GBA](http://www.palmettogba.com/) (http://www.palmettogba.com/). |
| Clinical investigation under a [Humanitarian Device Exemption](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048168.htm) | Is this a clinical research STUDY with a Humanitarian Device?  **Yes** - See CMS Guidance (next column).  **No** – Coverage Analysis is not required outside of a study. | Seek CMS approval consistent with the clinical research study design, specifications and details. These studies will be evaluated and managed on a case-by-case basis. |

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| Optional- Comments |

NOTE: Investigational devices are NOT yet FDA-approved devices/uses for marketing. The FDA has issued guidance that any off-label uses of FDA-Approved devices should generally be considered “**Investigational**” and covered under the applicable category listed above. VCU sponsor-investigators should consult with the [VCU OVPRI Integrity and Compliance.](http://www.research.vcu.edu/integrity_compliance/index.htm)

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| **Section C: CMS Review Documentation** |
| The VCU investigator must attach documentation to support one of the following (Ref: [CMS-Approved IDE Studies](https://www.cms.gov/medicare/coverage/ide/approved-ide-studies.html)):  CMS Approval obtained by the external sponsor or obtained as the Sponsor-Investigator.  CMS Approval received from Palmetto GBA.  Certify that CMS approval is not required. |
| Click to enter optional comments |

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| **Section D: Determination and Certification** |
| ***Based upon the above, does this study meet the standards for qualification under CMS/Medicare?***  **Yes** – To Complete your Coverage Analysis Package, prepare a Billing Plan indicating coverage as approved by CMS and attach all documentation for submission.  **No** – To complete your Coverage Analysis Package, prepare a Billing Plan indicating that the sponsor/funding entity will pay ALL study specific clinical services/items and attach all documentation for submission.  ***For participants covered by private insurance, prior authorization must be obtained from the insurance company.***  ***The PI understands and accepts the responsibilities outlined by CMS for this study, as the:***  Principal Investigator or  Sponsor-Investigator  **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School or Center Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |